4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16, 801, 803, 806, 810, 814, 820, 821, 822, and 830

[Docket No. FDA-2017-D-6841]

Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices; Immediately in Effect Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the guidance for industry and FDA Staff entitled "Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices; Immediately in Effect Guidance for Industry and Food and Drug Administration Staff." This guidance describes FDA's intention with respect to the enforcement of unique device identification requirements for certain class I and unclassified devices. FDA does not intend to enforce standard date formatting, labeling, and Global Unique Device Identification Database (GUDID) data submission requirements under Agency regulations for these devices before September 24, 2020. In addition, FDA does not intend to enforce direct mark requirements under an Agency regulation for these devices before September 24, 2022. The policy described in this guidance does not apply to implantable, life-supporting, or life-sustaining devices. The guidance document is immediately in effect, but it remains subject to comment in accordance with the Agency's good guidance practices.

DATES: The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2017-D-6841 for "Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices; Immediately in Effect Guidance for Industry and Food and Drug Administration Staff." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the

body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled "Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices; Immediately in Effect Guidance for Industry and Food and Drug Administration Staff" to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002 Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: *For Center for Devices and Radiological Health-regulated devices*: Loretta Chi, Unique Device Identifier Regulatory Policy Support, 301-796-5995, email: GUDIDSupport@fda.hhs.gov. *For Center for Biologics Evaluation and Research-regulated devices*: Stephen Ripley, Office of Communication, Outreach, and Development, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911, or call 1-800-835-4709 or 240-402-8010.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance entitled "Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices; Immediately in Effect Guidance for Industry and Food and Drug Administration Staff." In the September 24, 2013, *Federal Register* (78 FR 58786), FDA published a final rule establishing a unique device identification system designed to adequately identify medical devices during their distribution and use (the UDI Rule). Under § 801.20 (21 CFR 801.20) a device is required to bear a unique device identifier (UDI) on its label and packages unless an exception or alternative applies. Special labeling requirements apply to stand-alone software regulated as a device (§ 801.50 (21 CFR 801.50)). Under § 830.300 (21 CFR 830.300) data pertaining to the key characteristics of each device required to bear a UDI must be submitted to the GUDID. Devices that must bear UDIs on their labels and that are intended to be used more than once and reprocessed between uses must be directly marked with a UDI (§ 801.45 (21 CFR 801.45)). In addition, § 801.18 (21 CFR 801.18) requires certain dates on device labels to be in a standard format.

UDI requirements are being phased in over 7 years according to a schedule of compliance dates established in the UDI Rule ranging from September 24, 2014, to September 24, 2020.

The compliance dates established for class I and unclassified devices--other than implantable, life-supporting, or life-sustaining (I/LS/LS) devices--are September 24, 2018, for labeling, GUDID submission, and standard date format requirements, and September 24, 2020, for direct mark requirements.

FDA does not intend to enforce standard date formatting, UDI labeling, and GUDID data submission requirements under §§ 801.18, 801.20, 801.50, and 830.300 for class I and unclassified devices, other than I/LS/LS devices, before September 24, 2020. FDA also does not intend to enforce direct mark requirements under § 801.45 for these devices before September 24, 2022. This policy does not apply to class I devices that FDA has by regulation exempted from the good manufacturing practice requirements because such devices are excepted from UDI requirements (see § 801.30(a)(2) (21 CFR 801.30(a)(2))).

In addition, finished class I and unclassified devices, other than I/LS/LS devices, manufactured and labeled prior to September 24, 2018, are excepted from UDI labeling requirements under §§ 801.20 and 801.50, as well as from GUDID data submission requirements for a period of 3 years after the established compliance date or until September 24, 2021. (See §§ 801.30(a)(1) and 830.300(a).) We also do not intend to enforce standard date format requirements under § 801.18 during that same 3-year period for finished class I and unclassified devices, other than I/LS/LS devices, manufactured and labeled before September 24, 2018.

Pursuant to § 801.30(a)(1), finished class I and unclassified devices, other than I/LS/LS devices, manufactured and labeled prior to September 24, 2018, would also be excepted from direct marking requirements until September 24, 2021. However, with the exception of I/LS/LS devices, we do not intend to enforce direct mark requirements before September 24, 2022, for class I and unclassified devices (including those manufactured and labeled prior to September

24, 2018). We believe this policy regarding direct mark compliance dates is appropriate because it is not in the best interest of the public health for labelers of class I and unclassified devices to prioritize remediating devices in inventory to meet direct mark requirements prior to addressing direct marking, and its impact on the safety and effectiveness, for devices manufactured following labelers' full implementation of UDI.

Fully realizing the benefits of the unique device identification system depends on UDI being integrated into data sources throughout our health care system, including in the supply chain, electronic health records, and registries. This requires UDI data to be of a high quality such that all stakeholders in the health care community have sufficient confidence in the accuracy and completeness of that data.

To fully reap the public health benefits and a return on investment of the unique device identification system, the Agency intends to focus its resources on addressing existing implementation challenges and optimizing the quality and utility of UDI data for higher-risk devices before focusing on UDI implementation issues for lower-risk devices. Undertaking this endeavor now will help ensure the transition from development of the unique device identification system to widespread use and sustainability.

This guidance is being implemented without prior public comment because the Agency has determined that prior public participation is not feasible or appropriate (§ 10.115(g)(2) (21 CFR 10.115(g)(2))). FDA has determined that this guidance document presents a less burdensome policy that is consistent with public health. Although this guidance is immediately in effect, FDA will consider all comments received and revise the guidance document as appropriate.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (§ 10.115). The guidance represents the current thinking of FDA on "Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices; Immediately in Effect Guidance for Industry and Food and Drug Administration Staff." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm. A search capability for all Center for Biologics Evaluation and Research guidance documents is available at https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm. This guidance document is also available at https://www.regulations.gov. Persons unable to download an electronic copy of "Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices; Immediately in Effect Guidance for Industry and Food and Drug Administration Staff" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 17029 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 801 have been approved under OMB control number 0910-0485 and the collections of information in 21 CFR part 830 have been approved under OMB control number 0910-0720.

Dated: January 9, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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